

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)
CORPORATION,)
Plaintiff,)
v.) C.A. No. 23-975-RGA
LIQUIDIA TECHNOLOGIES, INC.,)
Defendant.)

STIPULATION AND PROPOSED ORDER TO EXTEND TIME

WHEREAS, final FDA approval of Liquidia Technologies, Inc.’s (“Liquidia”) New Drug Application No. 213005 for its Yutreptia product is enjoined by the Court’s Final Judgment in C.A. No. 20-755-RGA until expiration of United Therapeutics Corporation’s (“UTC”) U.S. Patent No. 10,716,793 (*see* C.A. No. 20-755, D.I. 436);

WHEREAS, in C.A. No. 20-755 Liquidia has filed a Motion pursuant to Federal Rule of Civil Procedure 60(b) (“Rule 60(b) Motion”) for relief from the Final Judgment, which motion is currently pending before the Court (C.A. No. 20-755, D.I. 461);

WHEREAS, UTC has alleged in this action that Liquidia’s Yutreptia product for the treatment of pulmonary hypertension associated with interstitial lung disease (“PH-ILD”) infringes UTC’s U.S. Patent No. 11,826,327 (D.I. 1);

WHEREAS, if the Court grants Liquidia’s Rule 60(b) Motion, Liquidia would be permitted to, and intends to, launch its proposed Yutreptia product for treatment of pulmonary arterial hypertension (“PAH”) immediately and for treatment of PH-ILD upon the expiration of UTC’s regulatory exclusivity on March 31, 2024;

WHEREAS, UTC has filed a Motion for Preliminary Injunction in this action to enjoin Liquidia's launch of Yutrepia for treatment of PH-ILD upon the expiration of UTC's regulatory exclusivity on March 31, 2024 (D.I. 25);

WHEREAS, on February 21, 2024, UTC filed an action against the Food and Drug Administration ("FDA") in the United States District Court for the District of Columbia (*United Therapeutics Corp. v. Food and Drug Administration*, No. 24-cv-484-JDB) ("UTC-FDA Action") seeking to prevent the FDA from granting final approval to Liquidia's NDA for Yutrepia for the PH-ILD indication;

WHEREAS, on March 4, 2024, in the UTC-FDA Action, UTC filed a motion for a temporary restraining order and preliminary injunction that, if granted, would enjoin the FDA from granting final FDA approval to Liquidia's NDA for Yutrepia and thus result in enjoining Liquidia from launching the Yutrepia product for the treatment of PH-ILD, resulting in effectively the same relief UTC seeks here;

WHEREAS, UTC intends to immediately move for a Temporary Restraining Order to prevent the launch of Yutrepia for treatment of PH-ILD in the event the Court grants Liquidia's Rule 60(b) Motion; and

WHEREAS, the parties have conferred on a briefing schedule for UTC's pending Motion for Preliminary Injunction;

IT IS HEREBY STIPULATED AND AGREED by the parties, subject to the approval of the Court, that the time for Liquidia to respond to UTC's Motion for Preliminary Injunction (D.I. 25) is extended through and including April 5, 2024 and the time for Plaintiff to file a reply brief is extended through and including April 19, 2024. The foregoing schedule shall not bar or limit

UTC from moving for a Temporary Restraining Order should the Court grant Liquidia's Rule 60(b) Motion.

/s/ Michael J. Flynn

Jack B. Blumenfeld (No. 1014)
Michael J. Flynn (No. 5333)
MORRIS, NICHOLS, ARSHT
& TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisonichols.com
mflynn@morrisonichols.com
Attorneys for Plaintiff

Dated: March 8, 2024

/s/ Emily S. DiBenedetto

Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
Emily S. DiBenedetto (No. 6779)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
Attorneys for Defendant

SO ORDERED this _____ day of _____ 2024.

United States District Court Judge